



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0795]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Third-Party Review Under the Food and Drug Administration Modernization Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with medical devices third-party review under the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, daniel.gittleson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices; Third-Party Review Under FDAMA--21 U.S.C. 360m (OMB Control Number 0910-0375)--Extension

Section 210 of the Food and Drug Administration Modernization Act (FDAMA) established section 523 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360m), directing FDA to accredit persons in the private sector to review certain premarket notifications (510(k)s). Participation in this third-party review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation to FDA. Accredited third-party reviewers have the ability to review a manufacturer's 510(k) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation to FDA. Third-party reviewers should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually a period of 3 years.

This information collection will allow FDA to continue to implement the accredited person review program established by FDAMA and improve the efficiency of 510(k) review for low- to moderate-risk devices.

Respondents to this information collection are businesses or other for-profit organizations.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden

| Activity | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|--|--------------------|---------------------------------|------------------------|-----------------------------|-------------|
| Requests for accreditation | 1 | 1 | 1 | 24 | 24 |
| 510(k) reviews conducted by accredited third parties | 10 | 26 | 260 | 40 | 10,400 |
| Total | | | | | 10,424 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden

| Activity | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
|----------------|----------------------|---------------------------------|----------------------|----------------------------------|-------------|
| 510(k) reviews | 10 | 26 | 260 | 10 | 2,600 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

I. Reporting

510(k) Reviews Conducted by Accredited Third Parties

According to FDA's data, the number of 510(k)s submitted for third-party review is approximately 260 annually, which is 26 annual reviews per each of the 10 accredited reviewers.

II. Recordkeeping

Third-party reviewers are required to keep records of their review of each submission. According to FDA's data, the Agency anticipates approximately 260 submissions of 510(k)s for third-party review per year.

Dated: July 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.